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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:

Barone, Jr. et al.

Serial No.: 10/775574

Filed: February 9, 2004

Atty. File No.: 5370-7

For: "COMPOSITIONS FOR  
ENHANCING SEXUAL  
RESPONSIVENESS"

) Group Art Unit: 1614

) Examiner:

SUPPLEMENTAL INFORMATION  
DISCLOSURE STATEMENT

CERTIFICATE OF MAILING

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING  
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SHERIDAN ROSS P.C.

BY: [Signature]

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

The references cited on attached Form PTO-1449 are being called to the attention of the Examiner.

☒ Copies of the cited non-patent and/or foreign references are enclosed herewith.

☐ Copies of the cited U.S. patents and/or patent applications are enclosed herewith.

☒ Copies of the cited U.S. patents/patent application publications are not enclosed in accordance with the waivers dated July 11, 2003 and October 19, 2004, whereby patent applications filed, regardless of the filing date, need not submit copies of U.S. patents and U.S. patent application publications.

☐ Copies of the cited references are not enclosed, in accordance with 37 C.F.R. 1.98(d), because the references were cited by or submitted to the U.S. Patent and Trademark Office in prior application Serial No. \_\_\_\_\_ filed \_\_\_\_\_, which is relied upon for an earlier filing date under 35 U.S.C. § 120.

☐ To the best of applicants' belief, the pertinence of the foreign-language references are believed to be summarized in the attached English abstracts and in the figures, although applicants do not necessarily vouch for the accuracy of the translation.

☐ Examiner's attention is drawn to the following co-pending applications, copies of which have been or are being submitted:

Serial No. \_\_\_\_\_ filed \_\_\_\_\_

Serial No. \_\_\_\_\_ filed \_\_\_\_\_

☐ Other: \_\_\_\_\_

Submission of the above information is not intended as an admission that any item is citable under the statutes or rules to support a rejection, that any item disclosed represents analogous art, or that those skilled in the art would refer to or recognize the pertinence of any reference without the benefit of hindsight, nor should an inference be drawn as to the pertinence of the references based on the order in which they are presented. Submission of this statement should not be taken as an indication that a search has been conducted, or that no better art exists.

It is respectfully requested that the cited information be expressly considered during the prosecution of this application and the references made of record therein.

#### FEES

|                                     |  |
|-------------------------------------|--|
| <input checked="" type="checkbox"/> | <p><b>37 CFR 1.97(b):</b> No fee is believed due in connection with this submission, because the information disclosure statement submitted herewith is satisfies one of the following conditions ("X" indicates satisfaction):</p> <ul style="list-style-type: none"><li><input type="checkbox"/> Within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d), or</li><li><input type="checkbox"/> Within three months of the date of entry into the national stage of an international application as set forth in 37 CFR 1.491 or</li><li><input checked="" type="checkbox"/> Before the mailing date of a first Office Action on the merits, or</li><li><input type="checkbox"/> Before the mailing of a first Office action after the filing of a request for continued examination under 37 CFR 1.114.</li></ul> <p>Although no fee is believed due, if any fee is deemed due in connection with this submission, please charge such fee to Deposit Account 19-1970.</p>  |
| <input type="checkbox"/>            | <p><b>37 CFR 1.97(c):</b> The information disclosure statement transmitted herewith is being filed after all the above conditions (37 CFR 1.97(b)), but before the mailing date of one of the following conditions:</p> <ul style="list-style-type: none"><li>(1) a final action under 37 C.F.R. 1.113 or</li><li>(2) a notice of allowance under 37 C.F.R. 1.311, or</li><li>(3) an action that otherwise closes prosecution in the application.</li></ul> <p>This Information Disclosure Statement is accompanied by:</p> <ul style="list-style-type: none"><li><input type="checkbox"/> A Certification (below) as specified by 37 C.F.R. 1.97(e). Although no fee is believed due, if any fee is deemed due in connection with this submission, please charge such fee to Deposit Account 19-1970.</li></ul> <p style="text-align: center;">OR</p> <ul style="list-style-type: none"><li><input type="checkbox"/> Please charge Deposit Account 19-1970 in the amount of \$180.00 for the fee set forth in 37 C.F.R. 1.17(p) for submission of an information disclosure statement. Please credit any overpayment or charge any underpayment to Deposit Account 19-1970.</li></ul> |

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|--------------------------|--|
| <input type="checkbox"/> | <p><b>37 CFR 1.97(d):</b> This Information Disclosure Statement is being submitted after the period specified in 37 CFR 1.97(c).</p> <p style="padding-left: 40px;"> <input type="checkbox"/> This information Disclosure Statement includes a Certification (below) as specified by 37 C.F.R. 1.97(e)<br/> AND<br/> <input type="checkbox"/> Applicants hereby requests consideration of the reference(s) disclosed herein. Please charge Deposit Account 19-1970 in the amount of \$180.00 under 37 C.F.R. 1.17(p). Please credit any overpayment or charge any underpayment to Deposit Account 19-1970. Election to pay the fee should not be taken as an indication that applicant(s) cannot execute a certification. </p> |
|--------------------------|--|

**Certification (37 C.F.R. 1.97(e))**  
(Applicable only if checked)

- ☐ The undersigned certifies that:
- ☐ Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement. 37 C.F.R. 1.97(e)(1).  
☐ A copy of the communication from the foreign patent office is enclosed.
- OR
- ☒ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement. 37 C.F.R. 1.97(e)(2).

Respectfully submitted,

SHERIDAN ROSS P.C.

By: Robert D. Traver  
Robert D. Traver  
Registration No. 47,999  
1560 Broadway, Suite 1200  
Denver, Colorado 80202-5141  
(303) 863-9700

Date: 17 JUNE 2005



Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT****Complete if Known**

|                        |                  |
|------------------------|------------------|
| Application Number     | 10/775574        |
| Filing Date            | February 9, 2004 |
| First Named Inventor   | Barone, Jr.      |
| Art Unit               | 1614             |
| Examiner Name          |                  |
| Attorney Docket Number | 5370-7           |

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|-------|---|----|---|
| Sheet | 1 | of | 4 |
|-------|---|----|---|

**U.S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No. <sup>1</sup> | Document Number<br>Number-kind Code <sup>2 (if known)</sup> | Publication Date   | Name of Patentee of<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
|--------------------|-----------------------|---|--------------------|--|---|
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|                    | 2.                    | US-5,232,935  | August 3, 1993     | 5,232,935  |   |
|                    | 3.                    | US-5,240,945  | August 31, 1993    | 5,240,945  |   |
|                    | 4.                    | US-5,318,960  | June 7, 1994       | 5,318,960  |   |
|                    | 5.                    | US-5,428,070  | June 27, 1995      | 5,428,070  |   |
|                    | 6.                    | US-5,451,407  | September 19, 1995 | 5,451,407  |   |
|                    | 7.                    | US-5,496,827  | March 5, 1996      | 5,496,827  |   |
|                    | 8.                    | US-5,543,430  | August 6, 1996     | 5,543,430  |   |
|                    | 9.                    | US-5,595,753  | January 21, 1997   | 5,595,753  |   |
|                    | 10.                   | US-5,767,160  | June 16, 1998      | 5,767,160  |   |
|                    | 11.                   | US-5,891,459  | April 6, 1999      | 5,891,459  |   |
|                    | 12.                   | US-5,895,658  | April 20, 1999     | 5,895,658  |   |
|                    | 13.                   | US-5,922,332  | July 13, 1999      | 5,922,332  |   |
|                    | 14.                   | US-5,985,860  | November 16, 1999  | 5,985,860  |   |
|                    | 15.                   | US-6,007,824  | December 28, 1999  | 6,007,824  |   |
|                    | 16.                   | US-6,117,872  | September 12, 2000 | 6,117,872  |   |
|                    | 17.                   | US-6,207,713  | March 27, 2001     | 6,207,713  |   |
|                    | 18.                   | US-6,294,517  | September 25, 2001 | 6,294,517  |   |
|                    | 19.                   | US-6,323,211  | November 27, 2001  | 6,323,211  |   |
|                    | 20.                   | US-6,368,640  | April 9, 2002      | 6,368,640  |   |
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|                    | 24.                   | US-6,548,087  | April 15, 2003     | 6,548,087  |   |

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| Examiner Signature |  | Date Considered |  |
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\*EXAMINER: Initial if reference is considered, whether or not citation is in conformance and not considered. Include copy of this form with next communication to applicant.

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| Substitute for form 1449A/PTO<br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b> |   |    |   | <b>Complete if Known</b> |                  |
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| Examiner Name   |   |    |   |                          |                  |
| Sheet   | 2 | of | 4 | Attorney Docket Number   | 5370-7           |

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|--|-----|-----------------|-------------------|---------------|--|
|  | 25. | US-6,548,841    | October 1, 2002   | 6,458,841     |  |
|  | 26. | US-6,579,543    | June 17, 2003     | 6,579,543     |  |
|  | 27. | US-6,646,006    | November 11, 2003 | 6,646,006     |  |
|  | 28. | US-2002-0151592 | October 17, 2002  | 20020151592A2 |  |
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|  | 31. | US-2004-0102358 | May 27, 2004      | 20040102358A1 |  |

| FOREIGN PATENT DOCUMENTS |                       |                           |                     |                                   |                                |  |   |                |
|--------------------------|-----------------------|---------------------------|---------------------|-----------------------------------|--------------------------------|--|---|----------------|
| Examiner Initials*       | Cite No. <sup>1</sup> | Foreign Patent Document   |                     |                                   | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear | T <sup>6</sup> |
|                          |                       | Country Code <sup>2</sup> | Number <sup>4</sup> | Kind Code <sup>5</sup> (if known) |                                |  |   |                |
|                          |                       | PCT                       | -                   |                                   |                                |  |   |                |
|                          |                       |                           | -                   |                                   |                                |  |   |                |
|                          |                       |                           | -                   |                                   |                                |  |   |                |
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|                          |                       |                           | -                   |                                   |                                |  |   |                |
|                          |                       |                           | -                   |                                   |                                |  |   |                |
|                          |                       |                           | -                   |                                   |                                |  |   |                |
|                          |                       |                           | -                   |                                   |                                |  |   |                |

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| Examiner Initials*   | Cite No. <sup>1</sup> |   |
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|  | 33.                   | Cellek S, Moncada S, Nitrgic neurotransmission mediates the non-adrenergic non-cholinergic responses in the clitoral corpus cavernosum of the rabbit. Br. J. Pharmacol. 125(8):1627-9 (1998).     |
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| Examiner Signature |  | Date Considered |  |
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|   |   |    |   | Art Unit                      | 1614             |
|   |   |    |   | Examiner Name                 |                  |
| Sheet   | 3 | of | 4 | Attorney Docket Number 5370-7 |                  |

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| 50. | Park JK, Kim JU, Lee SO, Hwang PH, Yi HK, Kim YG, Cho KW, Nitric oxide-cyclic GMP signaling pathway in the regulation of rabbit clitoral cavernosum tone. Exp. Biol. Med. 227(11):1022-30 (2002).   |
| 51. | Sample of CONNECTION™ packaging including ingredient list, enclosed herewith.   |
| 52. | Sivamani RK, Stoeber B, Wu GC, Zhai H, Liepmann D, Maibach H., Clinical microneedle injection of methyl nicotinate: stratum corneum penetration. Skin Res. Technol. 11(2):152-6 (2005).   |
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|   |   |    |   | Filing Date              | February 9, 2004 |
|   |   |    |   | First Named Inventor     | Barone, Jr.      |
|   |   |    |   | Art Unit                 | 1614             |
|   |   |    |   | Examiner Name            |                  |
| Sheet   | 4 | of | 4 | Attorney Docket Number   | 5370-7           |

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|  | 54. | Web page from the Better Business Bureau of Metropolitan New York, Inc., April 21, 2005.   |
|  | 55. | Woolfson AD, Malcolm RK, Campbell K, Jones DS, Russell JA., Rheological, mechanical and membrane penetration properties of novel dual drug systems for percutaneous delivery. J Control Release. 3;67(2-3):395-408 (2000). |

|                       |  |                    |  |
|-----------------------|--|--------------------|--|
| Examiner<br>Signature |  | Date<br>Considered |  |
|-----------------------|--|--------------------|--|

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